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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,215	03/09/2004	Scott T. Moore	10000-353	2716

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EXAMINER

FOSTER, MARLEE CHRISTINE

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 11/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/796,215

Applicant(s)

MOORE ET AL..

Examiner

Marlee C. Foster

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>07/15/2004; 01/14/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 5-10, 23-28, and 30-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilson et al. (US Patent 6,425,898). Wilson et al. disclose a stent delivery system comprising an introducer tube (24), a pusher assembly that includes a first tubular portion (16) and a second tubular portion (18), the second tubular portion including a flexible portion 17 with a greater degree of flexibility than the first tubular portion (col. 5, lines 15-44). Wilson et al. disclose the second portion comprises a stent-loading portion and pusher members (21, 22) that engage the stent to slide it into position (col. 4, lines 15-27). As shown in the figure 5, the diameter of the second portion is smaller than the diameter of the first portion. Wilson et al. discloses a radiopaque filler in the pusher member (col. 6, lines 18-22). Wilson et al. disclose the pusher 22 may be formed of materials known in the art, including polytetrafluoroethylene (col. 5, lines 59-65). Regarding claims 7, 8, and 9, Wilson et al. disclose the second tubular portion comprised of a metal-reinforced polymer material (70), including braided polyimide tubing (col. 5, lines 27-35). The second tubular portion may also be composed of Nitinol (col. 5, line 32). The proximal surface of the

pusher member, subject to lateral bending stresses, would open kinks as the martensite phase transforms back into the austenite phase of the shape memory metal in the system.

As shown in the figures, Wilson et al. disclose the second tubular portion extending to the distal tip, with the stent-carrying portion and flexible section being one element, with the distal tip being tapered to receive the stent (figures 4-6). In figure 3, the pusher member has a diameter equal to or greater than the stent (20b).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

Art Unit: 3731

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claim 4 rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. (US Patent 6,425,898) in view of Kugler et al. (US Patent 6,790,222). Wilson et al. disclose a stent delivery system, and the structures of an introducer tube, a pusher member, a first and second tubular portion, and a distal tip. However, Wilson et al. fail to teach the pusher member composed of a low density polymer. Kugler et al. teach a similar delivery system, with an outer layer designed to reduce friction, and an inner layer (190) composed of a low-density polyethylene. The low density polyethylene in Kugler et al. provides some resilience in the outer sheath. Therefore, it would have been obvious to one of ordinary skill in the art to manufacture the pusher member of Wilson et al. from a low density polymer.

7. Claims 11-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. (US Patent 6,425,898) in view of Kugler et al. (US Patent 6,790,222). Wilson et al. disclose a stent delivery system substantially as claimed, and the structures of an introducer tube, a pusher member, a first and second tubular portion, and a distal tip. The pusher members are configured to slidably deploy the stent from the introducer catheter. Wilson et al. fail to disclose the soft pusher member composed of a low density polymer. Kugler et al. teach a similar stent delivery system, with an

Art Unit: 3731

introducer catheter comprised of a polytetrafluoroethylene outer sheath to reduce friction. The inner sheath is composed of a low density polyethylene, to provide resilience to the system while maintaining stability when stresses are applied.

Therefore, it would have been obvious to one of ordinary skill in the art to manufacture the pusher member of Wilson et al. from a low density polymer in view of the teachings of Kugler et al.

8. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. (US Patent 6,425,898) in view of Kugler et al. (US Patent 6,790,222).

Wilson et al. disclose a stent delivery system substantially as claimed, comprising an introducer catheter with a distal end and a distal portion, a stent preloaded within the distal portion, a pusher assembly including a pusher member configured to slidably deploy the stent. The pusher assembly includes a first and second tubular portion, with a flexible section that is configured to adjust to lateral bending stresses within the body without kinking. Wilson et al. fails to disclose the soft pusher member composed of a low density polymer.

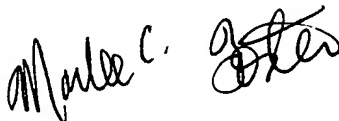
Kugler et al. teach a sheath comprised of a low density polymer, configured to add resilience while maintaining structural stability. Kugler et al. additionally teach the importance of maintaining resistance to stresses on the body, to minimize the stress that the stent is subjected to, which may cause premature fatigue fractures. Therefore, it would have been obvious to one of ordinary skill in the art to manufacture the pusher member of Wilson et al. from a low density polymer.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marlee C. Foster whose telephone number is (571) 272-5072. The examiner can normally be reached on Monday to Friday 8:00am to 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



MCF

Marlee C. Foster
Examiner
Art Unit 3731



ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

10/30/06